REMARKS

The November 23, 2005 Office Action required restriction under 35 U.S.C. 121 and 372 from among the following four groups.

I. Claims 1-9 and 28-36 drawn to a method of treating allergy;

II. Claims 10-23, 28-36 and 42 drawn to a method of treating infection;

III. Claims 24-36 and 43 drawn to a method of treating cancer;

IV. Claims 37-41 drawn to a chitin composition and delivery device.

The Office Action also required election of a specific allergen from claims 2-6 of Group I; and a specific pathogen from the claims of Group II.

For the purpose of examination, Applicants hereby elect Group I and the species "aeroallergens" **with traverse**. However, Applicants respectfully request that the restriction requirement and the requirement for election of species be reconsidered and withdrawn in view of the remarks herein.

The Office Action has improperly applied a PCT "unity of invention" standard in making the present requirements for restriction and election of species. Applicants believe that U.S. restriction practice should have been employed because the present application was filed as a continuation-in-part application under 37 C.F.R. 111, not as a national stage application under C.F.R. 371. However, regardless of whether the PCT or U.S. standards are applied, the requirement for restriction and election of species is not proper, and is traversed as follows.

I. RESTRICTION REQUIREMENT

A. Requirement for restriction under PCT rule 13.2 is not proper

The Office Action alleges that the claims of Groups I-IV lack unity of invention because they do not relate to a single inventive concept under PCT Rule 13.2. In particular, the Office Action alleges that the claims of Groups I-IV lack a "special technical feature" that defines a contribution over Shibata et al. and WO 97/20576. PCT Rule 13.2 states that

> *"Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression* ***"special technical features" shall mean those technical features that define a contribution which each of the***

claimed inventions, considered as a whole, makes over the prior art."

(emphasis added).

Although the application of PCT rule 13.2 in making the present restriction requirement is believed to be improper, in order to be fully responsive to the present Office Action applicants hereby traverse the requirement, as follows.

The claims of Groups I-IV all recite the "technical feature" of chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation. This technical feature is not taught by either Shibata et al. or WO 97/20576. Hence the technical feature of chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation is novel contribution over the prior art. Furthermore, the technical feature of chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation is also an inventive contribution over the prior art, as it is not taught or suggested by the combination of Shibata et al. and WO 97/20576. Shibata et al. involves only oral administration of chitin particles. WO 97/20576 does not involve chitin at all, but instead involves chitosan. Furthermore, WO 97/20576 relates to use of chitosan as a vaccine adjuvant to increase the immune response against antigens. Thus, the description of WO 97/20576 states *"We have now found surprisingly that, upon intranasal co-administration, chitosan enhances the immune response of antigens and thus provides an adjuvant effect."* Because WO 97/20576 teaches that nasal administration of chitosan increases immune response, one of skill in the art would **not** expect chitosan to be useful for treating allergic reactions to allergens, and would not be motivated to modify the teaching of WO 97/20576 to use chitin in place of chitosan for treatment of allergies. Accordingly, the technical feature of chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation is neither taught nor suggested by the prior art cited in the Office Action. Therefore, the feature of chitin microparticles having an average diameter of less than 10μm administered intranasally makes a contribution over the prior art and therefore qualifies as a "special technical feature" unifying the claims of Groups I-IV.

Furthermore, the MPEP states that *"the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority."* MPEP §1850. As can be seen from the attached copy of the International Preliminary Examination Report (IPER) of the parent application (PCT/GB02/03814;

publication number WO 03/015744), the International Preliminary Examining Authority did **not** find a lack of unity of invention (see IPER Part 3, Box IV). Furthermore, the Reasoned Statement in the IPER states that the claims are novel and possess inventive step over the prior art. Although the present application is a continuation-in-part of the parent PCT application, the claims differ only in respect to certain formalities, such as converting the claims from European style "use" claims to U.S. style "method" claims. The claims of the present application recite the same "special technical features" as recited in the claims of the parent PCT application. As such, the fact that the present application is a CIP should not be sufficient reason to justify disregarding the findings of the International Preliminary Examining Authority regarding unity of invention.

While it is normally justifiable for a U.S. Examiner to assert that the holding of an Examiner from a foreign office is of little probative value, this is so because the applicable rules for the respective countries are different. This is NOT the case with respect to lack of unity of invention, i.e. the same rules for unity of invention which apply to the present Examiner also applied to the Examiner of the PCT application and there has been no indication as to why the previous Examiner's decision was clearly erroneous. MPEP 706.04 strongly hints at the deference that is to be accorded to the findings by the previous patent examiner of an application – *"Full faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make a new search in the mere hope of finding something. >Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 139, 57 USPQ2d 1449, 1499-50 (D. Mass. 2001)." Therefore, any holding of lack of unity of invention should have also included a statement as to why the previous Examiner's action was a clear error. This statement will not be necessary in the Examiner's reply should restriction requirement be withdrawn by the Examiner.

In summary, the claims of Groups I-IV satisfy the unity of invention requirements of PCT Rule 13.2. Accordingly, reconsideration and withdrawal of the restriction requirement based on lack of unity under PCT Rule 13.2 is respectfully requested.

B. Requirement For Restriction Under 35 U.S.C. 121 Is Not Proper

Although the Office Action requires restriction on the basis of failure to satisfy the unity of invention requirement of PCT rule 13.2, Applicants respectfully assert that restriction would

not be proper even if U.S. restriction practice according to 35 U.S.C. 121 and 37 CFR 1.141-1.146 were applied.

The MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner. *Id.* The MPEP states that *"if the search and examination of all the claims in an application can be made without serious burden, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions."* *Id.* (Emphasis added).

It is respectfully submitted that the claims of Groups I-IV are not independent or distinct as the claims of all Groups relate to chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation. Furthermore, it is respectfully submitted that a search and examination of the claims of Groups I-IV can easily be performed without serious burden. Because the claims of Groups I-IV all involve chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation, it is inevitable that a search and examination of the claims of Groups I-IV will be co-extensive and will require a review of the same art. The fact that the International Searching Authority and the International Preliminary Examining Authority were able to perform a search and examination of all the claims of the present application together, without breaking the claims up into separate groups and/or requiring the payment of additional fees for search and examination, provides compelling evidence that such a search and examination of all of the claims of the present application can readily be performed without undue burden. Accordingly, the Examiner **must** examine all of the claims together. Performing a separate search and examination of the claims of Groups I-IV would be repetitive and inefficient, and would result in severe prejudice to the Applicant, both in terms of expense and time, particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed.

Furthermore, the present Office Action fails to make a proper requirement for restriction under 35 U.S.C. 121 or 37 CFR 1.141-1.146. The MPEP states that the *"examiner must provide reasons and/or examples to support conclusions"* when making a requirement for restriction, and that *"for purposes of the initial requirement, a serious burden on the examiner may be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02"*. MPEP §803. The Office

Action fails to provide any reasoning or evidence to show that the claims of Groups I-IV constitute inventions that are independent or distinct, and also fails to provide any reasoning or evidence to show that searching the claims of each of Groups I-IV would constitute an undue burden. Consequently, the Office Action can not be used to require restriction under 35 U.S.C. 121.

In summary, the requirement for restriction has not been shown to be proper, either under the PCT "unity of invention" standard or under U.S. restriction practice, especially since the claims of each of Groups I-IV contain the "special technical feature" of chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation, and the claims of each of Groups I-IV also represent subject matter that is interrelated and not distinct, and finally also because the requisite showing of serious burden in examining all of the claims has not been made, and the fact that the International Searching Authority and the International Preliminary Examining Authority have already been able to conduct such a search and examination provides compelling evidence that such a search and examination can be made without undue burden. Consequently, reconsideration and withdrawal of the restriction requirement is respectfully requested.

I. REQUIREMENT FOR ELECTION OF SPECIES

The Office Acton asserts that a species of allergen must be elected if the claims of Group I are elected and a species of pathogen must be elected if the claims of Group II are elected. As stated above, Applicants hereby elect the species "aeroallergens" from within Group I, with traverse.

The Office Action asserts that an election of species is required because the species do not relate to a general inventive concept under PCT Rule 13.1. As stated above, Applicants believe that PCT practice is not applicable here because the present application was filed as a continuation-in-part application under 37 C.F.R. 111, and not as a national stage application under C.F.R. 371. However, regardless of whether the PCT or U.S. standards are applied, the requirement for an election of species is not proper and is traversed, as follows.

Under PCT practice the requirement for an election of species is not proper. Election of species is a convention which may be applied by an Examiner **only** for applications eligible for U.S. restriction practice under 37 CFR §§1.141-1.146. Restriction practice for national stage

applications filed under 37 CFR 371 is governed by PCT standards according to 37 CFR §§1.475 and 1.499, which have no provisions for requiring an election of species.

Furthermore, even if U.S. restriction practice is employed, the requirement for an election of species is not proper. M.P.E.P. § 808.01(a) states that *"where there is no disclosure of relationship between species (see M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention is required"*. However, even where there is no disclosure of relationship between species, 37 CFR 1.141 provides that a reasonable number of species may still be claimed in one application if the other conditions of the rule are met.

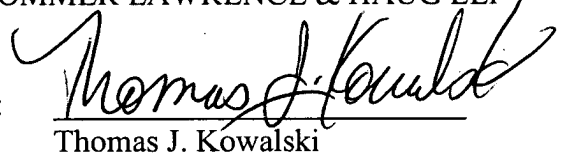
It is respectfully submitted that there is a disclosed relationship between the species of allergens and pathogens recited in the claims since the specification and claims disclose that they are all treatable using the chitin microparticles of the present invention when administered intranasally or by inhalation. Furthermore, Applicants submit that the number of species is sufficiently few that a search and examination of all species can be performed without undue burden. This is especially true because the search and examination of each species will likely be co-extensive and, in any event, will involve such interrelated art in the very narrow field of using chitin microparticles in medical treatments, that search and examination of the all of the species can be readily performed at the same time. Furthermore, the fact that the International Searching Authority and the International Preliminary Examining Authority were able to perform a search and examination including all of the species simultaneously provides compelling evidence that such a search and examination can readily be performed without undue burden.

In summary, the requirement for an election of species has not been shown to be proper, either under the PCT standard or under U.S. restriction practice, especially because there is a disclosed relationship between all of the species claimed and the number of species is sufficiently few that a search and examination of all species can readily be performed, as demonstrated by the fact that the International Searching Authority and the International Preliminary Examining Authority have already been able to conduct such a search and examination. Consequently, reconsideration and withdrawal of the requirement for an election of species is respectfully requested.

CONCLUSION

Reconsideration and withdrawal of the restriction and election of species requirements, and favorable examination on the merits, are respectfully requested.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Kiddle, Simon J.
MEWBURN ELLIS
York House
23 Kingsway
London, Greater London WC2B 6HP
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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	15.01.2004
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
SJKBP6085013	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB 02/03814	16.08.2002	16.08.2001

Applicant
MEDICAL RESEARCH COUNCIL et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	de Haas, B Tel. +31 70 340-4738

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SJKBP6085013	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 02/03814	International filing date *(day/month/year)* 16.08.2002	Priority date *(day/month/year)* 16.08.2001
International Patent Classification (IPC) or both national classification and IPC A61K9/00		
Applicant MEDICAL RESEARCH COUNCIL et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06.03.2003	15.01.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Rankin, R Telephone No. +31 70 340-4659

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 02/03814

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-36 as originally filed

Claims, Numbers

1-43 as originally filed

Drawings, Sheets

1-19 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-36
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-36
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Novelty

The examiner takes the view that claims 1-36 meet the requirements of Article 33(2) PCT. The differences between the documents cited in the search report and the application are outlined below:

D1: SHIBATA Y ET AL: 'Oral administration of chitin down-regulates serum IgE levels and lung eosinophilia in the allergic mouse.' JOURNAL OF IMMUNOLOGY (BALTIMORE, MD.: 1950) UNITED STATES 1 FEB 2000, vol. 164, no. 3, 1 February 2000 (2000-02-01), pages 1314-1321, XP002218084 ISSN: 0022-1767 cited in the application

- Chitin particles for oral use, not inhalable. No mention of compositions containing an allergen in conjunction with chitin particles.

D2: US-A-5 591 441

- No chitin particles in examples, no particle size, injectable, not inhalable. No mention of compositions containing an allergen in conjunction with chitin particles.

Regarding Inventive Step

The examiner accepts the arguments of the applicant and concedes that the application is inventive (Article 33(3) PCT) since documents D1 and D2 would not be combined by the skilled person in order to solve the problem posed.

The closest prior art is D1.

The difference between the application and this disclosure is that is that D1 describes the use of chitin particles in down regulating allergic responses in mice by administering the particles **orally**.

The effect of the difference is that the compositions of the application may be used to treat allergy in the respiratory tract.

The problem to be solved may therefore be considered as finding a method of treating respiratory allergic conditions.

The solution provided by the applicant is to deliver the chitin particles nasally or by

inhalation

This solution is inventive (Article 33(3) PCT) since neither D1 nor D2 suggest that administering chitin particles intranasally or by inhalation would solve the problem posed.